

OCT 22 1976
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PP# 6G1813 and FAP# 6H5136 Chlorothalonil (Daconil 2787) on mint and mint oil. Evaluation of analytical methods and residue data.

R. B. Perfetti, Chemist, Chemistry Branch
Registration Division (WH-567)

Minor Crops Officer and Toxicology Branch

THRU: Chief, Chemistry Branch

The Agricultural Experiment Station of Indiana requests the establishment of a 5.0 ppm temporary (1 year) tolerance for chlorothalonil (2,4,5,6-tetrachloro isophthalonitrile) in or on mint (hays) and a 500 ppm temporary food additive tolerance of chlorothalonil in mint oil. Permanent tolerances for chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile have previously been established on a variety of r.a.c.'s. These tolerances range from 0.1 ppm in or on potatoes to 15 ppm in or on celery. The petitioner does not propose that the 4-hydroxy metabolite of chlorothalonil (as defined in the Regulations) be included in the tolerance (Section 180.275).

Chlorothalonil petitions pending include PP#'s 6E1841, 6F1799 and 6E1761.

No letter from Diamond Shamrock Corporation authorizing the use of data in their files in support of this petition is included. This authorization should be obtained by the Minor Crops Officer.

Conclusions

- 1) The nature of the residue is adequately understood from data on other crops for this experimental use.
- 2) Adequate analytical methods are available for enforcement of the proposed temporary tolerances.
- 3a) Without residue data we can draw no conclusions as to the level of residues to be expected in fresh (green) mint hay.
- b) Residue data on mint oil is needed before we can determine whether a temporary food additive tolerance on mint oil is needed.

- 4a) Without residue data on spent mint hay we cannot categorize this use with respect to Section 180.6(a) for meat and milk. As an alternative, a label restriction against feeding spent mint hay could be imposed.
- b) No poultry feed items are involved, therefore this use falls into category 3 of Section 180.6(a) with respect to poultry and eggs.

Recommendations

We recommend that the proposed temporary tolerances not be established for the reasons given in conclusions 3a, 3b, and 4a above.

The petitioner should be advised that a favorable recommendation for the temporary tolerance(s) will require the following:

- 1) A revised Section F proposing the tolerance in terms of 2,4,5,6-tetrachloroisophthalonitrile and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile.
- 2) A letter from Diamond Shamrock Corporation (which may be obtained by the Minor Crops Officer) authorizing the use of data in their files in support of this petition.
- 3) Raw analytical data for green mint hay and mint oil including blank crop values, and sample chromatograms.
- 4) Residue studies reflecting the proposed conditions of use and analysis of fresh mint hay and mint oil.
- 5) In lieu of residue data for spent mint hay, a label restriction against the feed use of spent mint hay may be imposed.

It should also be noted that approval of the associated experimental use permit could be given in lieu of resolution of the deficiencies described above if the petitioner would agree to the addition of a crop destruction clause or other approved non-domestic-food disposal of the treated crop.

The above requirements in addition to the following will be required for a permanent tolerance.

- 1) Residue studies reflecting adequate geographical and varietal representation. The Minor Crops Officer should note that while the State of Indiana is proposing this tolerance, residue data from other mint growing areas will be needed for a permanent tolerance.
- 2) Recovery data for chlorothalonil and its 4-hydroxy metabolite from fresh (green) mint hay and mint oil reflecting fortification levels of the same order of magnitude as the proposed tolerances.

Formulation

The formulation proposed for this experimental use is Diamond Shamrock Corporation's Bravo(R) 6F. Bravo (R) 6F contains 6.0 lb of chlorothalonil/gal. All inerts in the formulation are cleared under Section 180.1001. Technical chlorothalonil is 95.6-98.5% pure; impurities in the product include [REDACTED]

[REDACTED] description of the manufacturing process was submitted in connection with PP# 4E 1502 and discussed in our review of that petition (memo of 11/27/74, R. Schmitt).

The possibility of HCB in the technical chlorothalonil was discussed in connection with PP# 4E1502 and we concur with the conclusion reached in that case (memo of 10/27/74, R. Schmitt), that no HCB residue problem exists from the use of chlorthalonil.

Proposed Use

Under this experimental use 120 lb of active ingredient is to be used to treat 10 acres of mint in Indiana. The proposed use calls for post-emergence application (when plants are 6-8" tall) of 1.125 to 4.50 lb active ingredient/acre using ground equipment. Treatments are to be made at 7-10 day intervals to a maximum of 4 applications per season. No PHI is specified.

Nature of the Residue

No new metabolism studies were submitted with this petition.

The metabolism of chlorothalonil was most recently reviewed by CHM in connection with PP# 6E1761 (memo of 5/11/76, W. S. Cox). The residue in plants is mainly surface in nature and consists of the parent and the 4-hydroxy metabolite. We conclude that, for this experimental use the nature of the residue in mint is adequately defined from data on other crops.

Analytical Method

The current method of enforcement is a glc procedure which utilizes an electron capture detector to determine both the parent and the 4-hydroxy metabolite in separate analyses.

IMPURITY INFO IS NOT INCLUDED

This method has undergone a successful method trial for both the parent and the 4-hydroxy metabolite on peanuts fortified at 0.3 and 0.6 ppm and on broccoli fortified at 2.5 and 5.0 ppm.

We conclude that for the purposes of this petition adequate analytical methods are available for enforcement of the temporary tolerance on fresh mint hay and mint oil.

Residue Data

No residue data was submitted with this petition. We do not feel that any of the residue data on chlorothalonil in our files can be translated to mint. Therefore we can draw no conclusions as to the level of residue to be expected in fresh mint hay and mint oil. An approximate calculation of the maximum residues possible in fresh mint hay and mint oil is all that can be made. If mint is treated 4 times with 4.5 lb. active ingredient/acre (Note: This reflects the maximum number of treatments and the maximum application rate.), and assuming that all the residue occurs on the fresh mint hay the maximum residues which could occur on the fresh mint hay could be ca 6000 ppm. Calculated residues in the oil would even be higher.

We do not believe that these calculations are an accurate reflection of the residues likely to result from this use. Actual residue data for fresh mint hay and for mint oil are needed in order for us to draw any conclusions as to an appropriate tolerance level.

Meat, Milk, Poultry, and Eggs

The only feed item involved in this use is spent mint hay which is usually plowed back into the soil but may make up the 25% of the diet of beef cattle and spring finishing lambs, and up to 60% of the diet of dairy cattle. Without residue data we cannot draw any conclusions as to the possible transfer of residues to meat and milk. We will therefore require a label restriction prohibiting feeding of spent mint hay to livestock.

There are no poultry feed items involved with this use so this use falls in category 3 of Section 180.6(a) with respect to poultry and eggs.

R. B. Perfetti, Ph.D.

cc:TOX:EEE, FDA, OHM (5)
WH-567:RBPERFETTI:mer:Rm 108:WSME:X62610:10/21/76
RDI:RSQUICK:m10/7/76:JGCUMMINGS:10/8/76